

ABSTRACT

210061036-013002
An assay method and kit is disclosed for detecting the presence of at least one
predesignated, target antibody to a mycobacterium in a sample selected from one or more patient
bodily fluids. The method comprises the following steps: (a) contacting the sample of one or
5 more patient bodily fluids with at least one mycobacterium antigen on a lateral-flow assay
membrane to bind to the target antibody in the sample; (b) previously, simultaneously or
subsequently to step (a), binding the at least one mycobacterium antigen with a conjugated label
producing a detectable signal; and (c) detecting the signal whereby the presence of the target
antibody is determined in the sample by the intensity or presence of the signal. The method can
further comprise the step of evaluating immunization status of the patient from whom the sample
came by comparing the signal or lack thereof with immunizations previously received by the
patient and in comparison to a known standard control. In a preferred embodiment, the
mycobacterium antigen specifically binds to *Mycobacterium tuberculosis* specific antibodies.
Preferably, the immunoassay of the present invention comprises a lateral-flow assay comprising
15 a membrane, a conjugated label pad, and at least one mycobacterium antigen bound to the
membrane. In a preferred embodiment, the at least one mycobacterium antigen is selected from
the group consisting of 38kDa and 16kDa antigens.